REMARKS

This application has been reviewed in light of the Office Action dated October 1, 2009. Claims 46-59 and 65-90 are presented for examination, of which Claim 46 is in independent form. Favorable reconsideration is respectfully requested.

Claims 46 - 59 and 65 - 90 have been rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over U.S. Patent No. 6,626,950 B2 to Brown et al. (Brown) in view of U.S. Patent No. 5,141,510 to Takagi et al. (Takagi). Applicants respectfully traverse this rejection in view of the following remarks.

The present invention is directed to a triphasic prosthetic device having a base component that is comprised of a synthetic ceramic that can be anchored in or onto an osteochondrial environment. The independent claim makes clear that at least 50% of the highly oriented hollow bodies of the polymeric hollow body component are aligned perpendicular to the plane of the articulating surface of the base component. The presently claimed device provides a prosthetic articular cartilage material which has an improved structural stability and provides for accurate positioning in the bone. In addition, the device of this invention is made of materials that are biomechanically able to withstand normal joint forces and to promote repair and replacement of cartilage tissue or cartilage-like tissue. It is respectfully submitted that the advantageous device of the present invention is not disclosed or suggested by the prior art of record.

Brown describes an implantable device comprising a foamed polymer (scaffold) and a ceramic base component (column 3, lines 13 to 22). The polymeric part of this implant is a

porous polymer produced in a foaming process (column 5, lines 40 to 57). Further, it is generally described in column 4, lines 8 to 11, that the polymer may have channels that run through the porous polymer foam for improved cell invasion, vascularization and nutrient diffusion.

The Examiner states that Brown does not "explicitly" teach that more than 50%, or more than 90% or 95%, of the highly oriented hollow bodies of the polymeric hollow body component are aligned perpendicularly to a plane of an articulating surface of the base component. In fact, there is no such disclosure in Brown, either explicitly or implicitly.

As previously noted, Claim 46 of the present application is directed to a triphasic prosthetic device comprising a polymeric hollow body component with a number of highly oriented hollow bodies wherein more than 50% of said number of highly oriented hollow bodies of the polymeric hollow body component are aligned perpendicularly to a plane of an articulating surface of the base component. The present specification makes clear (page 5, last paragraph of the International Publication), that the stability of the prosthetic device is essentially improved by this number of highly oriented hollow bodies which are aligned essentially in parallel to the insertion axis of the prosthetic device, i.e., perpendicularly to the plane of the articulating surface. Further, these hollow bodies form a brush-like structure in a direction perpendicular to the base component (see page 7, last paragraph of the International Publication). In addition, these highly oriented hollow bodies may change alignment direction and self-organize at the uppermost end of the brush-like structure which can occur under pressure (by the surgeon) after implantation. (See page 8, first paragraph of the International Publication). Moreover, the instant specification makes clear that the greater the percent alignment, the more preferred is the inventive device.

According to the present invention, the hollow bodies of the prosthetic device must have the highly organized orientation in order to ensure stability of the device when implanted in the defect side in the joint. (See last paragraph of page 5 of the International Publication stating "[i]t has been surprisingly found that the stability of a prosthetic articluar cartridge device can be improved ...".) Brown does not recognize or suggest a highly specific orientation of the channels. There is clearly no embodiment showing an implant having provided these highly oriented channels. Thus, the extremely high degree of hollow body alignment is not taught or suggested by Brown.

The Examiner further refers to particular descriptions in the Brown patent: the micropores at the interface between the ceramic polymeric part (column 3, lines 49 to 50) and the porosity of the ceramics is provided by leachable inclusions, molds with pore forming pins or drilling (column 6, lines 56 to 60). According to the present invention, however, the highly oriented channels are not provided in the ceramic but in the polymeric part of the prosthetic device.

Furthermore, the micropores in the foam do not entail any orientation (see column 4, lines 5/6) and the micro-patterning of pores is limited to the surface (column 4, lines 11/12). Also, the interlocking of ceramic and polymer base and their intrinsic porosity does not entail the highly-oriented hollow bodies as required in the prosthetic device of the present invention.

Accordingly, the Examiner's conclusion that it would have been obvious to try orientation of the recited bodies is without basis and it's not supported by the cited art. Brown provides no guidance whatsoever as to how porous polymer foam could even be made so as to have highly oriented bodies. Thus, no reasonable basis has been provided by the Examiner as to why a person of ordinary skill in the art would even try to make highly oriented hollow bodies

that are aligned perpendicular to the plane of the articularly surface of a base component using the foam polymer of Brown.

In addition, the Examiner's assertion that Brown would inherently disclose the superficial layer comprising randomly oriented fibers is without basis. Inherency requires that a disclosure will necessarily provide each and every time what is asserted to be inherent. The disclosure of Brown clearly does not teach a device having randomly oriental fibers each and every time it is made.

Lastly, the Examiner's apparent assertion on page 5 of the office action that the "wherein" clause of claim 46 is not limiting is not well taken. MPEP2111.01, simply indicates that an Examiner should carefully consider whether a "wherein" clause is limiting. However, the same section makes clear that when such a clause is material to patentability, it must be considered. In present claim 46, the wherein clause clearly sets forth a limitation related to the structure of the claimed device.

The deficiencies of Brown are not remedied by Takagi. Takagi describes an implantable device for bone based on calcium phosphate only (see abstract). It is explicitly described in column 4, lines 55 to 60 that the structure of the artificial bone for implantation can be applied for insert, fill-up or cover of a defect or removed portion of a living bone. Takagi is not applicable for repairing cartilage material. Thus, the skilled person would not have considered Takagi when looking for a way to develop a prosthetic device for repairing or replacing cartilage or cartilage-like tissue.

Accordingly, Applicants respectfully submit that the art of record, whether taken alone or together, does not disclose or suggest the presently claimed invention.

In view of the foregoing remarks, Applicants respectfully request favorable reconsideration and early passage to issue of the present application.

Applicants' undersigned attorney may be reached in our New York Office by telephone at (212) 218-2100. All correspondence should continue to be directed to our address listed below.

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